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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,896	08/08/2006	Junji Takeda	490051.402USPC	7212

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EXAMINER	
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ART UNIT	PAPER NUMBER
1633	

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/563,896	Applicant(s) TAKEDA ET AL.	
	Examiner Fereydoun G. Sajjadi	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 56-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 and 56-106 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-25 and 56-106 are pending in the application.

#### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-25, 63, 64 and 66-87, drawn to an isolated nucleic acid, a nucleic acid fragment, or a gene cassette having a nucleic acid sequence encoding a transposon, wherein the nucleic acid sequence has a methylation at at least one nucleotide; a vector and composition comprising the same; a kit, and a nucleic acid introduction system comprising said nucleic acid and a transposase.

Group II, claim(s) 56- 62 and 65, drawn to a method for producing a transgenic organism comprising transforming a germ cell of a desired organism with a nucleic acid sequence encoding a transposon, wherein the nucleic acid sequence has a methylation at at least one nucleotide and regenerating an organism using the transformed germ cell.

Group III, claim(s) 88-91 drawn to a method for producing a transgenic organism comprising introducing into a pluripotent cell, a transposase and a nucleic acid sequence located between at least two inverted repeat sequences, wherein the nucleic acid sequence has at least one nucleotide methylated, and growing the cell in a living body.

Group IV, claim(s) 92- 105, drawn to an *in vitro* method for introducing a nucleic acid and a transposase into a DNA of a cell comprising introducing a nucleic acid fragment that comprises a nucleic acid sequence located between at least two inverted repeat sequences and wherein at least

one nucleotide of said nucleic acid is methylated; and a method of transposing a nucleic acid in a cell *in vitro* comprising introducing said nucleic acid fragment and transposase into a cell.

Group V, claim(s) 92-105, drawn to an *in vivo* method for introducing a nucleic acid and a transposase into a DNA of a cell comprising introducing a nucleic acid fragment that comprises a nucleic acid sequence located between at least two inverted repeat sequences and wherein at least one nucleotide of said nucleic acid is methylated; and a method of transposing a nucleic acid in a cell *in vivo* comprising introducing said nucleic acid fragment and transposase into a cell.

Group VI, claim(s) 106, drawn to a method for identifying a gene in a cell comprising introducing into a cell a nucleic acid that comprises a nucleic acid sequence located between at least two inverted repeat sequences and wherein at least one nucleotide of said nucleic acid is methylated; digesting the DNA in the cell; identifying the inverted repeat sequence and comparing the sequence with sequence information in a database.

37 CFR 1.475 (e) states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.”

In view of 37 CFR 1.475 (e), Groups IV and V are considered a plurality of the inventions listed in claims 92-105.

Please note that PCT Rule 13.2, no longer specifies the combinations of categories of invention which are considered to have unity of invention. The categories of invention in former PCT Rule 13.2 have been replaced with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-VI, is a nucleic acid sequence encoding a transposon, wherein the nucleic acid sequence is methylated in at least one nucleotide.

Groups I-VI do not share a special technical feature over the art because the inventions lack an inventive step under PCT Article 33(3) as being obvious over Ros et al. (Genetics 157:1723-1733; April 2001). Ros et al. teach the regulation of the maize transposable elements Ac/Ds by DNA methylation. (Title and Abstract). Specifically teaching that Ds elements that are hemi-methylated on one DNA strand transpose in the absence of replication (first column, p. 1724), and that the methylation on the top strand of the Ds element inverted repeat efficiently binds to transposase resulting in a hyperactive Ds element (first column, p. 1732).

The claims in Groups I-VI are drawn to distinct products, and methods that utilize distinct steps, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

The inventions of Groups I, and II-VI constitute product and related processes. MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specifically named single species of transposon such as hobo, Ac, Tam, Ac/Ds, P element, Tc1, mariner or sleeping beauty, as recited on pp. 2-3 of the specification, or SEQ ID NOS: 1-3 and 10-26 of the specification; and a corresponding specifically named single species of transposase, with corresponding SEQ ID NO.

A specifically named single species of recipient host cell, as recited on p. 84 of the specification, and a specifically named single species of transgenic biological organism, from the species recited on pp. 105-107 of the specification and claim 91.

A specifically named single species of nucleic acid fragment (promoter, enhancer or silencer), from the species recited in claim 69.

A specifically named single species of DNA (cellular genome, episome or plasmid), from the species recited in claim 75.

A specifically named single species of nucleic acid introduction system (particle bombardment, electroporation, microinjection, gene introduction reagent or virus vector), from the species recited in claim 87.

A specifically named single species of pluripotent cell (oocyte, embryo, egg or stem cell), from the species recited in claim 89.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 13, 14, 25, 56, 59, 63, 65, 66, 81, 88, 92, 101 and 106, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 1-106

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features (transposons, host cells, biological organisms, nucleic acid fragment, introduction systems and pluripotent cells) linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature, the requirement for unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (571) 272-3311. The examiner can normally be reached on 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Fereydoun G. Sajjadi, Ph.D.  
Examiner, A.U. 1633